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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,508	02/15/2002	Kathryn F. Sykes	UTSD:557USD5/MBW	5374

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EXAMINER	
AKHAVAN, RAMIN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/077,508	SYKES ET AL.	
	Examiner	Art Unit	
	Ray Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *88-93 and 97-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-93 and 97-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or

120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Applicant has attempted, in the transmittal papers to claim priority for the nonprovisional 09/535, 366 but neglected to check the box to add the amendment (see attached p. 4 of transmittal).

Information Disclosure Statement

Certain foreign references disclosed have not been considered as they are not in English and applicant has not expressed their having any relevance.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See Spec. at 30 ¶2 and 95 ¶2. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 89, 90, 93 and 97-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 89, 90 and 93 contain the trademark/trade name PCR®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an open reading frame or DNA segment within the expression element and, accordingly, the identification/description is indefinite.

Claim 91 is vague and indefinite as drafted because it is unclear whether the deoxyuridines are incorporated into the expression elements themselves or some other stretch of DNA. Furthermore it is unclear to what kind of complementary stretch applicant is referring. Presumably the complementary stretches are DNA stretches in the PCR primers used to produce the expression elements.

When referring to the base claim, claims 97-104 recite "method of..." making the claims indefinite. The base claims are drawn to a composition, thus the dependent claims should make the appropriate reference (e.g. "The expression element of..."). However, based on the context of the base claims and dependent claims, it is presumed that applicant is referring to the process steps in the base claims, thus the claims will be examined accordingly (*See infra*, discussion of product-by-process-type claims). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 88-89, 97-98 and 102-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Heim et al (U.S. Patent No. 5,447,862, issued 1995) (see whole document).

The claims are drawn to a composition – linear or circular expression elements – encompassing a complete gene including promoter, coding sequence and terminator. Claim 88 from which all other claims depend is a product-by-process claim, which is not limited whatsoever by the manipulations of the recited steps but rather only limited to the structure or composition of the product, thus patentability is determined by the product itself and not a method of production. See MPEP §2113. Put another way applicant's invention is drawn to any expression construct (e.g. plasmid, vector or linear fragment comprising a promoter, enhancer, open reading frame and terminator), thus is anticipated absent evidence to the contrary, by any characterized expression construct produced through any method in the art. As written the

claims are anticipated by any construct capable of expressing an open reading frame (i.e. gene) no matter in what cell or under what circumstance.

Subsequent claims that do not alter the structure of the composition to which the claims are drawn, but merely modify the process by which the expression constructs are made, are not dispositive, absent evidence to the contrary, as to whether the claim is anticipated or not. Claims 100 and 104 do modify the composition of claim 88 where the promoter or terminator is from a eukaryote.

Heim et al. teach expression systems (meaning any DNA sequence encoding a polypeptide comprising promoter, gene and terminator) comprising genes under control of eukaryotic regulatory sequences, including promoters and terminators. (e.g. Abstract, Figs. 2-6, col. 4 lines 43-45). Thus Heim et al. anticipate claims 88-89, 97-98 and 102-104.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 90-93, 99 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heim et al. (US Patent No. 5,447,862) as applied to claims above, and further in view of Rashtchian (Curr. Opin. Biotech., 6:30-36 (1995)).

The claims are drawn to non-covalently linking DNA segments comprising the composition of linear or circular expression elements.

Heim et al. teach the composition of expression elements but it does not teach non-covalent linking of DNA segments (*See supra*, for what Heim et al. teach). As such the composition of applicant's invention is different structurally from what Heim et al. teach, because the annealed DNA constructs in applicant's invention would contain nicks at the termini where DNA segments hybridize, where the ligated DNA constructs from Heim et al. would not contain such nicks (e.g. ligase-repaired nicks).

Rashtchian teaches a method of non-covalently linking DNA segments using PCR primers incorporating deoxyuridines (dUMP) in every third position, where the PCR product contains dUMP-containing 5' is treated with uracil DNA glycosylase (UDG) exposing 3' overhangs, facilitating subsequent annealing of the DNA segment to a vector backbone containing complementary sequence (see whole document, e.g. p. 31, Fig. 1). Rashtchian does not explicitly use a vector backbone with promoters and terminators, but as discussed above, that is what Heim et al. teach.

It would have obvious to one of skill in the art at the time of the invention to use the non-covalent recombinant technology that Rashtchian teaches to produce expression elements with various promoters or terminators, because Heim et al. teach that it is within the skill of the art to construct such an expression element. One would have been motivated to so in order to receive the expected benefit of rapid construction of novel genes and DNA constructs (e.g. Rashtchian, p. 35, ¶ 4). UDG cloning provides an efficient method for cloning a variety of PCR DNA fragments and significantly increases the options available to the molecular biologist. (Id.) Absent evidence to the contrary there would have been a reasonable expectation of success in incorporating UDG cloning to engineer expression constructs. Therefore the claims above are not patentable.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure includes: Johnston et al. (U.S. Patent No. 5,703,057); Petitclerc et al (J. Biotech., 40:169-178 (1995) (see whole article); and Li et al. (Gene Therapy, 4:449-54 (Jan. 1997)). Johnston et al teach engineering of libraries comprising expression constructs including promoters and terminators, including eukaryotic terminators (see whole document, e.g. Fig. 1A-D). Furthermore Johnston et al contemplate using DNA segments themselves rather than plasmids as expression elements (col. 15, lines 45-54). Petitclerc et al. teach design and construction of expression vectors with promoters, ORFs and terminators, which include promoters and terminators from a eukaryote (e.g. see Abstract, pp. 170-71 and Fig. 1). Li et al teach plasmid-based expression elements (see whole doc., e.g. Abstract).

Conclusion

Claim for priority is defective. All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 703-305-4454. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD, can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.